SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Exorex Lotion 5% v/w Cutaneous Emulsion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient is coal tar solution 5% v/w.

Excipients with known effect

Methyl hydroxybenzoate (E218)	0.10% w/w
Propyl hydroxybenzoate (E216)	0.05% w/w
Hydrogenated polyoxyl castor oil	0.45% w/w

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous emulsion

A smooth mustard coloured emulsion.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Exorex is for the treatment of psoriasis of the skin and scalp.

4.2 Posology and method of administration

Adults and children over 12 years of age
Ensure that the lesions are clean. Apply a thin layer of Exorex two to three times per day to the affected areas. Massage gently and leave to dry.

For young children under 12 years of age and the elderly
The emulsion may be diluted by mixing with a few drops of freshly boiled and cooled water in the palm of the hand.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Presence of folliculitis and acne vulgaris.

Exorex should not be used on patients who have disease characterised by photosensitivity such as lupus erythematosus or allergy to sunlight.

Exorex should not be applied to inflamed or broken skin (open exuding wounds or infection of the skin).

4.4 Special warnings and precautions for use

Coal tar may cause skin irritation. If irritation occurs, the treatment should be reviewed and discontinued if necessary.

Coal tar enhances photosensitivity of the skin, and exposure to direct sunlight after application of Exorex should be avoided.

Use with care near the eyes and mucous membranes. If any emulsion should accidentally enter the eye, flush with normal saline solution or water.

Do not apply to genital and rectal areas.

Apply with caution to the face.

Hydrogenated polyoxyl castor oil may cause skin reactions. Methyl and propyl hydroxybenzoates may cause allergic reactions that might be delayed.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other Medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in pregnant and lactating women but coal tar preparations have been in use for many years without apparent ill-consequence and no harmful effects on the health of the child is anticipated with the proper use of this product. However, it is recommended that the use of coal tar in pregnancy and lactation be restricted to intermittent use, in a low concentration on a relatively small percentage of body surface and that use during the first trimester be avoided.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Skin and subcutaneous tissue disorders:

Skin irritation, photosensitivity of the skin. In addition coal tar may cause acne-like eruptions of the skin.

An increased risk of skin cancer in psoriatic patients treated with a combination of coal tar and UVB radiation has been reported. However epidemiological studies of patients treated with coal tar alone are inconclusive. The risk of toxicity should be taken into account when considering the suitability of this product for the patient (see also section 5.3).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

There is no evidence that overdose of topical Exorex would be harmful other than possibly inducing a hypersensitivity to coal tar. Ingestion of Exorex may require gastric lavage depending on the quantity taken and should be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Tars, ATC code: D05AA

Exorex contains coal tar, an antipruritic and keratoplastic. It is used in eczema, psoriasis and other skin conditions. Tar acids have also been shown to have disinfectant properties. Exorex may be used alone, or as part of a more extensive treatment regimen.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

In animal studies coal tar has been shown to increase the incidence of epidermal carcinomas and self-limiting keratoacanthomas.

While the ingredients of coal tar have been shown to express genotoxic properties, epidemiological studies with patients have been shown to be inconclusive concerning the potential carcinogenic risks of coal tar products in human long term treatment. Nevertheless the possible risk of prolonged treatment should be taken into account when considering the usage of the product.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

dl-Alpha tocopherol
Vitamin F ethyl ester
Xanthan gum
Propyl hydroxybenzoate (E216)
Methyl hydroxybenzoate (E218)
Hydrogenated polyoxyl castor oil
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High density polyethylene bottle containing titanium dioxide.
Polypropylene green flip-top caps.

Pack sizes: 100 and 250ml
A professional sales pack of 30ml is also available.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Shake the bottle before use.

7. MARKETING AUTHORISATION HOLDER

Teva UK Limited,

Ridings Point,

Whistler Drive,

Castleford,

WF10 5HX, United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00289/2306

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3 November 1999/23 May 2007

10. DATE OF REVISION OF THE TEXT

24/04/2023